

**REMARKS**

Amendment to claim 25 is to insert a punctuation mark. Amendment to claim 37 is for the purpose of clarifying what Applicants regard as the invention. No new matter has been added.

I. **ALLOWED CLAIMS**

Applicants wish to thank the Examiner for allowing claims 12-20.

II. **CLAIM RESTRICTION**

In response to the restriction requirement, claims 42-49 have been canceled with traverse. According to the Office Action, claims 22-28 and 42-49 are withdrawn from consideration. However, Applicants respectfully note that multiple actions on the merits for claims 22-28 have already been received in previous Office Actions and responded by Applicants. As such, it would be prejudicial to the Applicants to have claims 22-28 restricted out at this late stage of the prosecution. For at least the foregoing reason, Applicants respectfully request that claims 22-28 be considered in view of the amendment and arguments (repeated herewith) presented in Applicants' last response.

III. **CLAIM OBJECTIONS UNDER 35 U.S.C. § 112**

Claims 37-41 stand objected to for the specification allegedly failed to teach how to acquire multiple images in a physiological cycle. Applicants do not understand the objection since such step is simply performed by taking multiple images while a patient is moving (e.g., breathing). As such, those skilled in the art can clearly perform such step without undue experimentation. In addition, Applicants respectfully submit that techniques for acquiring multiple images in a physiological cycle

are known in the art, and that those skilled in the art know how to perform such step in view of the specification. For example, page 7 of the specification describes an apparatus 20 that can be used to take a plurality of images while at least a portion of a patient is undergoing a physiological cycle.

#### IV. CLAIM REJECTIONS UNDER 35 U.S.C. § 102/103

Claims 1-7, 9, 10, 34, and 37-39 stand rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent No. 6,307,914 (Kunieda). Applicants respectfully note that in order to sustain a rejection under §102, each element in the rejected claim must be found, either expressly or inherently, in the cited reference.

##### Claims 1-10

Claims 1 and 10 each recites establishing a relationship of the at least one marker relative to the target by measuring a relative position between the at least one marker and the target. According to the Office Action, column 11, line 59 to column 12, line 9 allegedly disclose the above limitation. Applicants respectfully disagree. As shown in figure 7 that corresponds to the cited passage, the marker in Kunieda is placed at a center of the target position, and it is assumed that aiming the marker will automatically result in an aiming of the target. As such, Kunieda does not disclose or suggest, but in fact teaches away from, the above limitation. For at least the foregoing reason, claims 1 and 10, and any claims depending therefrom, are believed allowable over Kunieda.

##### Claims 22-28

Claim 25 recites adjusting *a shape* of a radiation beam. Kunieda does not disclose or suggest such limitation. According to the Office Action, column 16, lines 25-37 of Kunieda discloses the above limitation. However, the cited passage actually discloses:

In the above embodiment 1, on/off control of the medical treatment beam 16 of the linac 15 is performed by obtained three-dimensional coordinates of the tumor marker 17. However, as shown in FIG. 20, if the moving body pursuit irradiating device is constructed such that the multi-leaf collimator 15a is opened and closed by the multi-leaf collimator control section 35 by performing an inverse operation from a moving amount of the tumor marker 17 and an irradiating field is dynamically controlled, the position of a tumor can be set to an irradiating object of the medical treatment beam at any time. Accordingly, unnecessary exposure due to a fluoroscope is restrained and a medical treatment time can be shortened.

As such, the cited passage does not disclose or suggest adjusting a shape of a radiation beam, as recited in claim 25. Also according to the Office Action, the term “inverse operation” refers to opening one side of a collimator while closing another side of the collimator to maintain a tumor centered in a beam. However, even under this interpretation, all of the collimator leafs would move such that the same beam shape is maintained. For at least the foregoing reason, claim 25 and its dependent claims 22-24 and 26-28 are believed allowable over Kunieda.

Claims 34, 40, and 41

Claim 34 recites using an internal anatomy of a patient as a marker, and *establishing a relationship of the marker relative to the target*. According to the Office Action, columns 1 and 2 of Kunieda allegedly discloses such limitations. However, Applicants respectfully note that columns 1 and 2 of Kunieda discloses locating a “diseased part S” which is the treatment position. Because in Kunieda, the anatomy being detected is coextensive with the target, Kunieda does not disclose or suggest establishing a relationship of an internal anatomy marker relative to the target, and in fact, teaches away from such limitation. For at least the foregoing reason, claim 34 and its dependent claims are believed allowable over Kunieda.

Claims 37-39

Claim 37 has been amended to clarify that images are acquired during a *same* physiological cycle. Kunieda does not disclose or suggest such limitation. For at least the foregoing reason, claim 37 and its dependent claims are believed allowable over Kunieda.

V. INFORMATION DISCLOSURE STATEMENTS

Applicants wish to bring to the attention of the Patent Office the references listed on the two attached IDS', which were previously submitted on March 4, 2003 (please note that only the second page of form PTO/SB/08A has not been considered; the first page of form PTO/SB/08A has already been considered), and March 17, 2003, and requests that they be considered and initialed by the Examiner.

**CONCLUSION**


Based on the foregoing, all remaining claims are believed in condition for allowance. If the Examiner has any questions or comments regarding this amendment, please contact the undersigned at the number listed below.

The Commissioner is authorized to charge any fees due in connection with the filing of this document to Bingham McCutchen's Deposit Account No. 50-2518, referencing billing number 7012072001. The Commissioner is authorized to credit any overpayment or to charge any underpayment to Bingham McCutchen's Deposit Account No. 50-2518, referencing billing number 7012072001.

Respectfully submitted,

Bingham McCutchen LLP

Dated: 9/13/05

By:   
Gerald Chan  
Reg. No. 51,541

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Enclosures: Copies of previously submitted IDS'



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Date Mailed

Applicant(s)

Title:

Serial No.:

Commissioner for Patents  
Washington, DC 20231

SIR: Please place the U.S. Patent and Trademark Office date stamp hereon to acknowledge receipt of the following:

1. Second Supplemental Information Disclosure Statement with Certificate of Mailing ( 3 pages)
2. Forms PTO/SB/08A&B (2 pages)
3. Cited References (20)
4. Return Receipt Postcard

52099722.1/2018721-2187217053

Due Date:

Atty. Docket

\*N/A\*

270/234; 18721-7053  
(PCM:ct)

March 4, 2003

Yoshihiro Takai et al.

METHOD AND APPARATUS FOR IRRADIATING A TARGET

10/037,477

Filing Date:

January 2, 2002





PATENT  
270/234  
18721-7053

CERTIFICATE OF MAILING (37 C.F.R. § 1.8(a))

[X] I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date indicated below with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, Washington, D.C. 20231.

Date of Deposit: 3/4/03

Signature of Person Certifying: Carolyn Tobias

Printed Name: Carolyn Tobias

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Yoshihiro Takai et al.

Serial No.: 10/037,477

Filed: January 2, 2002

For: METHOD AND APPARATUS FOR  
IRRADIATING A TARGET

Group Art Unit: 2882

Examiner: Not yet assigned

SECOND SUPPLEMENTAL  
INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Washington, D.C. 20231

Sir:

In accordance with 37 CFR §§ 1.97 and 1.98, the items identified in this Information Disclosure Statement ("IDS") are brought to the attention of the Office. The items are listed on the attached form PTO/SB/08A. Copies of the items listed are enclosed herewith.

The items identified in this IDS may or may not be "material" pursuant to 37 CFR § 1.56. The submission thereof by Applicants is not to be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as "prior art" under 35 USC § 102 with respect to this invention unless specifically designated by Applicants as such.



PATENT  
270/234  
18721-7053

INFORMATION DISCLOSURE STATEMENT FILING PROVISION:

- ☒ This IDS is believed to be timely in that it is being submitted under 37 CFR § 1.97(b), that is (1) within three months of the filing date of the application, which is not a continued prosecution application filed under § 1.53(d) or (2) within three months of entry of the national stage as set forth in 37 CFR § 1.491; or (3) before the mailing of a first Office action on the merits; or (4) before the mailing of a first Office action after filing a request for continued examination under § 1.114. Thus, no fee is required.
- ☒ However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and charge the fee due under 37 CFR § 1.17(p) to the deposit account referenced below.
- ☐ However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and a statement under 37 CFR § 1.97(e) is included below, thus no fee is required.
- ☐ This IDS is being submitted under 37 CFR § 1.97(c), that is after mailing of a first Office Action on the merits, but before a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311.
- ☐ The fee due under 37 CFR § 1.17(p) is submitted herewith.
- ☐ A statement under 37 CFR § 1.97(e) is included below, thus no fee is required. In the event that this IDS is not received before a Final Action or a Notice of Allowance, then Applicant respectfully requests that the Office consider the filing of these papers to be submitted under 37 CFR § 1.97(d) and charge the fee due under 37 CFR § 1.17(p) to the deposit account below.
- ☐ This IDS is being submitted under 37 CFR § 1.97(d), that is after a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311, but before payment of the issue fee. A statement under 37 CFR § 1.97(e) is included below. The fee due under 37 CFR § 1.17(p) is submitted herewith.
- ☐ This IDS is being submitted under 37 CFR § 1.97(i), that is after a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311, but before payment of the issue fee.



PATENT  
270/234  
18721-7053

STATEMENT UNDER 37 CFR § 1.97(e):

- ☐ Each item contained in this IDS was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS.
- ☐ No item contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this statement after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this IDS.

PAYMENT AND/OR AUTHORIZATION TO CHARGE FEES:

- ☐ A check in the amount of \_\_\_\_\_ is enclosed for the above fee(s).
- ☒ The Commissioner is authorized to credit any overpayment and to charge any underpayment to Bingham McCutchen's Deposit Account No. 50-2518, referencing billing No. 18721-7053, for any fees required by the filing of these papers.

Respectfully submitted,

Dated: 3/4/03

By: 

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**SECOND SUPPLEMENTAL  
INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	10/037,477
Filing Date	January 2, 2002
First Named Inventor	Yoshihiro Takai
Art Unit	2882
Examiner Name	Not yet assigned
Attorney Docket No.	270/234; 18721-7053

**OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published	
	1	Balter, J. M. et al., "Daily targeting of intrahepatic tumors for radiotherapy," <i>Int J Radiat Oncol Biol Phys</i> , 2002, Jan 1:52(1), pp. 266-71	
	2	Cho, P.S. et al. "Cone-beam CT for radiotherapy applications," <i>Phys Med Biol</i> 1995;40: pp. 1863-1883.	
	3	Drake, D.G. et al. "Characterization of a fluoroscopic imaging system for kilovoltage and megavoltage radiography," <i>Med Phys</i> 2000;27: pp. 898-905.	
	4	Fahrig, R. et al., "Three-dimensional computed tomographic reconstruction using a C-arm mounted XR11: Imagebased correction of gantry motion non-idealities," <i>Med Phys</i> 2000;27:30-38.	
	5	Feldkamp, L.A. et al. "Practical cone-beam algorithm," <i>J Opt Soc Am A</i> 1984;1: pp. 612-619.	
	6	Groh, B.A. et al. "A performance comparison of flat-panel imager-based MV and kV conebeam CT," <i>Med Phys</i> 2002;29: pp. 967-975.	
	7	Jaffray, D.A. et al. "A radiographic and tomographic imaging system integrated into a medical linear accelerator for localization of bone and soft-tissue targets," <i>Int J Radiat Oncol Biol Phys</i> 1999;45: pp. 773-789.	
	8	Jaffray, D.A. et al. "Cone-beam computed tomography with a flat-panel imager: Initial performance characterization," <i>Med Phys</i> 2000;27: pp.1311-23.	
	9	Keall, P. J. et al., "[Abstract] Motion Adaptive X-ray Therapy: A feasibility study," <i>3<sup>rd</sup> Annual IMRT Symposium ABSTRACTS</i> , Chicago 2000 World Congress, July 24, 2000, Sheraton Chicago, Chicago, Illinois.	
	10	Keall, P. J. et al., "[Presentation] Motion Adaptive X-Ray Therapy; A Feasibility Study," Medical College of Virginia Hospitals, Virginia Commonwealth University.	
	11	Midgley, S., et al. "A feasibility study for megavoltage cone beam CT using commercial EPID," <i>Phys Med Biol</i> 1998;43: pp. 155-169.	

Examiner's  
SignatureDate  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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Sheet 2 of 2

Complete if Known

Application Number	10/037,477
Filing Date	January 2, 2002
First Named Inventor	Yoshihiro Takai
Art Unit	2882
Examiner Name	Not yet assigned
Attorney Docket No.	270/234; 18721-7053

**OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS**

12	Mosleh-Shirazi, M.A. et al. "A cone-beam megavoltage CT scanner for treatment verification in conformal radiotherapy," <i>Radiother Oncol</i> 1998; 48: pp. 319–328.
13	Nakagawa, K. et al. "Megavoltage CT-assisted stereotactic radiosurgery for thoracic tumors: Original research in the treatment of thoracic neoplasms," <i>Int J Radiat Oncol Biol Phys</i> 2000; pp. 48:449–457.
14	Plisani, L. et al. "Setup error in radiotherapy: On-line correction using electronic kilovoltage and megavoltage radiographs," <i>Int J Radiat Oncol Biol Phys</i> 2000; 47: pp. 825–839.
15	Ruchala, K.J. et al. "Megavoltage CT on a tomotherapy system," <i>Phys Med Biol</i> 1999; 44: pp. 2597–2621.
16	Siewerdsen, J.H. et al. "Cone-beam computed tomography with a flat-panel imager: Magnitude and effects of x-ray scatter," <i>Med Phys</i> 2001;28: pp. 220–231.
17	Siewerdsen, J.H., et al. "Optimization of x-ray imaging geometry (with specific application to flat-panel cone-beam computed tomography)," <i>Med Phys</i> 2000;27: pp. 1903–1914.
18	Swindell, W. et al., "Computed tomography with a linear accelerator with radiotherapy application," <i>Med Phys</i> , 10, pp. 416–420.
19	Uematsu, M. et al. "A dual computed tomography linear accelerator unit for stereotactic radiation therapy: A new approach without cranially fixated stereotactic frames," <i>Int J Radiat Oncol Biol Phys</i> 1996;35: pp. 587–592.
20	Uematsu, M. et al. "Intrafractional tumor position stability during computed tomography (CT)-guided frameless stereotactic radiation therapy for lung or liver cancers with a fusion of CT and linear accelerator (FOCAL) unit," <i>Int J Radiat Oncol Biol Phys</i> 2000;48: pp.443–448.

Examiner's  
Signature

Date  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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**Atty. Docket**

**270/234; 18721-7053  
(PCM:ct)**

**Applicant(s):**

**Yoshihiro Takai, et al.**

**Title:**

**METHOD AND APPARATUS FOR IRRADIATING A TARGET**

**Serial No.:**

**10/037,477**

**Filing Date:**

**January 2, 2002**

**Commissioner for Patents  
Washington, DC 20231**

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**52105062.1/2018721-2187217053**





**In re the Application of:**

Yoshihiro Takai, et al.

**Serial No.: 10/037,477**

**Filed: January 2, 2002**

## For: METHOD AND APPARATUS FOR IRRADIATING A TARGET

**Group Art Unit: 2882**

**Examiner: Not-Yet-Assigned**

**Commissioner for Patents**  
**Washington, D.C. 20231**

Sir:

In accordance with 37 CFR § 1.97 and 1.98, and , the items identified in this Information Disclosure Statement ("IDS") are brought to the attention of the Office. The items are listed on the attached form PTO/SB/08A (08-00). Copies of items 4 and 6 are enclosed for the convenience of the Examiner. Other references (items 1-3, 5, 7-8) are not enclosed since each item was submitted or cited in a parent application (Serial No. 09/178,383).

The items identified in this IDS may or may not be “material” pursuant to 37 CFR § 1.56. The submission thereof by Applicant is not to be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as “prior art” under 35 USC § 102 with respect to this invention unless specifically designated by Applicant as such.

**CERTIFICATE OF MAILING TRANSMISSION**  
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Date of deposit

Carolyn Tobias

Name of Person transmitting Paper

*Carolyn Thomas*  
Signature of Person depositing Paper



Patent  
270/234  
18721-7053

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- ☒ However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and charge the fee due under 37 CFR § 1.17(p) to the deposit account referenced below.
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- ☐ The fee due under 37 CFR § 1.17(p) is submitted herewith.
- ☐ A statement under 37 CFR § 1.97(e) is included below, thus no fee is required. In the event that this IDS is not received before a Final Action or a Notice of Allowance, then Applicant respectfully requests that the Office consider the filing of these papers to be submitted under 37 CFR § 1.97(d) and charge the fee due under 37 CFR § 1.17(p) to the deposit account below.
- ☐ This IDS is being submitted under 37 CFR § 1.97(d), that is after a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311, but before payment of the issue fee. A statement under 37 CFR § 1.97(e) is included below. The fee due under 37 CFR § 1.17(p) is submitted herewith.
- ☐ This IDS is being submitted under 37 CFR § 1.97(i); this IDS does not comply with either 37 CFR § 1.97 or § 1.98. Therefore it is requested to be placed in the file but not considered by the Patent Office. A statement under 37 CFR § 1.97(e) is included below.

STATEMENT UNDER 37 CFR § 1.97(e):

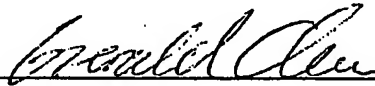
- ☐ Each item contained in this IDS was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS.
- ☐ No item contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this statement after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this IDS.

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- ☐ A check in the amount of \_\_\_\_\_ is enclosed for the above fee(s).
- ☒ The Commissioner is authorized to credit any overpayment and to charge any underpayment to Bingham McCutchen's Deposit Account No. 50-2518, referencing billing No. 18721-7053, for any fees required by the filing of these papers..

Respectfully submitted,  
BINGHAM McCUTCHEN LLP

Dated: 3/17/03

By:   
Gerald Chan  
Reg. No. 51,541

BINGHAM McCUTCHEN LLP  
Three Embarcadero, Suite 1800  
San Francisco, CA 94111-4067  
(650) 849-4400

**\*23639\***

**23639**

PATENT TRADEMARK OFFICE

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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

1

of

1

Complete if Known

Application Number

10/037,477

Filing Date

January 2, 2002

First Named Inventor

Yoshihiro Takai, et al.

Art Unit

2882

Examiner Name

Not yet assigned

Attorney Docket No.

270/234; 18721-7053

## **U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				

## **OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published
	1	Uematsu, Minoru, et al. "Daily Positioning Accuracy of Frameless Stereotactic Radiation Therapy with a Fusion of computed Tomography and Linear Accelerator (Focal) Unit: Evaluation of z-axis with a z-marker"; <i>Radiotherapy and Oncology</i> ; Vol. 50, Issue 3, 1 March 1999, Pages 337-339.

Examiner's  
SignatureDate  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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